PB86-247848

Pesticide Assessment Guidelines Subdivision N, Environmental Fate Series 165-2, Field Accumulation Studies on Rotational Crops. Addendum 1 on Data Reporting

(U.S.) Environmental Protection Agency
Washington, DC

Jun 86

U.S. Department of Commerce
National Technical Information Service
NTIS

50272-101

REPORT DOCUMENTATION PAGE	1. REPORT NO.	2.	3. Recipient's Accession No. PB86-247848/AS
4. Title and Subtitle: ADDENDUM 1 ON DATA REPORTING TO PESTICIDE ASSESSMENT GUIDELINES, Field Accumulation Studies on Rotational Crops			5. Report Date: June 1986 6.
7. Author(s): Samuel M. Creeger			8. Performing Organization Rept. No. 540/9-86-149
9. Performing Organization Name and Address: U.S. Environmental Protection Agency, OPP/HED (TS-769C), 401 M St. S.W., Washington, D.C. 20460			10. Project/Task/Work Unit No. 11. Contract(C) or Grant(G) No. (C) (G)
12. Sponsoring Organization Name and Address: Same as #9			13. Type of Report & Period Covered 14.

15. Supplementary Notes

Addendum 1 to Pesticide Assessment Guideline, Subdivision N, Chemistry: Environmental Fate (EPA-540/9-82-021 and NTIS Order Number PB83-153973), October, 1982

16. Abstract (Limit: 200 words)

The Data Reporting Guideline (DRG) for Field Accumulation Studies on Rotational Crops, Series 165-2, gives guidance to pesticide registrants on the format for their study report so that the Agency can review it efficiently. This guidance clarifies sections in the existing Pesticide Assessment Guidelines, Subdivision N, on data reporting. It provides an outline for the study report and describes the topics which should be addressed such as the composition of the product used, a map of the test plots, complete record of daily temperature and daily rainfall throughout the study, description of the handling of the samples, etc. Data submitters can use the DRG in preparing their reports for submission to EPA to meet 40 CFR 158 data requirements for the registration of pesticides.

The DRG for Series 165-2, Field Accumulation Studies on Rotational Crops is only one of a number of DRG's published by the National Technical Information Service as an addendum to Subdivision N of the Pesticide Assessment Guidelines.

17. Document Analysis a. Descriptors

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

18. Availability Statement	19. Security Class (This Report)	21. No. of Pages
Unclassified and freely available	Unclassified	14
	20. Security Class (This Page) Unclassified	22. Price $9.95

(See ANSI-Z39.18) See Instructions on Reverse OPTIONAL FORM 272 (4-77) (Formerly NTIS-35) Department of Commerce

EPA 540/9-86-149

PB86-247848

PESTICIDE ASSESSMENT GUIDELINES,

SUBDIVISION N,

ENVIRONMENTAL FATE,

Series 165-2,

Field Accumulation Studies on Rotational Crops,

ADDENDUM 1 ON DATA REPORTING,

Prepared by:

Samuel M. Creeger
Exposure Assessment Branch
Hazard Evaluation Division

Project Manager:

Elizabeth M.K. Leovey, Ph.D
Hazard Evaluation Division

Office of Pesticide Programs
U.S. Environmental Protection Agency

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U.S. DEPARTMENT OF COMMERCE
NATIONAL TECHNICAL
INFORMATION SERVICE
SPRINGFIELD, VA. 22161

Accession Number: PB83153973 u8308 10:56:11-09/30/86

(04) PC A06/MF A01

(05) Environmental Protection Agency, C 114
Washington, DC. Office of Pesticide Programs.

(06) Pesticide Assessment Guidelines, SS 1695 3390 + 20
Subdivision N, Chemistry: Environmental Fate.

(11) 18 Oct 82, (12) 114p MA 595 1190

(14)EPA-540/9-82-021

Message: ENTER: "END" FOR MENU.

Subdivision N - Field Accumulation Studies on Rotational Crops

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PESTICIDE ASSESSMENT GUIDELINES

ENVIRONMENTAL FATE

Field Accumulation Studies on Rotational Crops

Subdivision N, Section 165-2

DATA REPORTING

INTRODUCTION

A. Purpose

Information from this study enables the Agency to determine if rotational crops will take up pesticide residues under use conditions. The information is used to establish planting intervals for rotational crops and to determine if rotational crop tolerances should be considered.

B. Objective

This Data Reporting Guideline is designed to aid the petitioner/registrant in generating reports which are compatible with the Agency's review process. While following this Guideline is not mandatory, data submitters are encouraged to submit complete reports which can be efficiently reviewed by the Agency.

RESPONSE TO PUBLIC COMMENTS

There were 120 comments received from 13 commentors. The comments were grouped into 35 general comments.

A comment common to most of the commentors was that the data submission guidelines are being used as a mechanism to impose new data requirements. This document does not impose new data requirements but mentions the types of information submitted by registrants in the past with their field accumulation studies on rotational crops. The purpose of this document is to recommend the organizational format of that information. If the registrant feels some of the information will not aid in the efficient review of their study, then they may decide not to include it with the study. Conversely, if the registrant feels the information will aid in the efficient review of their study, then it would be to their advantage to include it with their study based on this recommended format.

After considering all the comments, it was obvious that many commentors do not understand how some information impacts heavily on the efficient review of a study. Therefore, in addressing the comments, an attempt has been made to explain how the information does aid in the efficient review of a study and that it will be in the registrant's interest to include that material with their study.

The comments are addressed below.

1. Comment - It is not important to know when the report was organized into final form.

   Response - The date in question as it will appear on the Title/Cover page is described in FR 49, 37930.

2. Comment - It is sufficient to ask for a single report number or other specific indicator.

   Response - The report identifier as it will appear on the Title/Cover page is described in FR 49, 37930.

3. Comment - It is inappropriate to include a name and telephone number of a contact person in the report since these may change after the report is submitted. In any case, questions from the Agency should be channeled through the registrant's Registration Department or through established Agency procedures.

   Response - As known (and desired) by most pesticide manufacturers, it is established Agency procedure for the Agency scientific reviewer to directly call the registrant, without involving the Agency Product Manager, to discuss technical aspects of the study. Therefore, to make Agency review of the study proceed efficiently, it is recommended that the name and telephone number of the contact person for that study (be it the registrant's Product Manager or science personnel) be made available.

4. Comment - There is no need for a list of figures and tables to appear in the Table of Contents.

   Response - Having this material in the Table of Contents will provide additional organization for the Agency reviewer and will allow more efficient review of the study.

5. Comment - The SUMMARY AND INTRODUCTION should be two separate sections. Also, the word SUMMARY should be changed to the word ABSTRACT.

   Response - These changes have been made.

6. Comment - Add "Age of Crop at Time of Sampling" and report residues in terms of parts per million in the summary table in the ABSTRACT.

   Response - These changes have been made.

7. Comment - Reporting "% parent and % products" goes beyond the requirements; total residues should be adequate.

   Response - We disagree. The Subdivision N Guidelines clearly call for analysis for residues of parent compound and degradates in the crops.

8. Comment - If the INTRODUCTION contains a statement that the study is designed to fulfill the EPA requirement for crop rotation, then the registrant will have to change this statement before using the same study to support registration in another country.

   Response - This Data Submission Guideline does not ask the registrant to provide a statement that the study is "to fulfill the EPA data requirement for crop rotation". We are sure the registrant can construct a sentence that will describe the purpose of the study and what requirement it is intended to satisfy that will be useful to both the Agency and other countries.

9. Comment - Since "primary crop" is mentioned in the INTRODUCTION AND SUMMARY, is bare soil application of the pesticide disallowed?

   Response - The study should be conducted under actual use conditions. If the pesticide is to be normally applied to bare soil, then this study should involve a bare soil application. If the pesticide is to be normally applied to a growing crop at a certain stage of growth, then this study should involve application to a growing crop.

10. Comment - Pesticide applications (for compounds other than the test compound) should be described by name, date applied and rate only.

    Response - This clarification has been made.

11. Comment - A ten year history of daily rainfall and temperature and how it compares to the daily rainfall and temperatures recorded during the study is not feasible.

    Response - Historical daily rainfall and temperature records from the nearest weather station are easily available and will be sufficient. When this information is submitted, it tells the Agency reviewer that either typical or atypical weather conditions occurred during the study and may impact on the study results. Delays may be encountered in the review of a report lacking this data while the reviewer obtains it from other sources.

12. Comment - It is not necessary to provide crop and pesticide use history on the test plot for the five year period preceding the study.

    Response - This information is not required but should it be submitted, it should be included in the materials section discussing the crop. It is recommended that the available crop and pesticide use history be submitted.

13. Comment - The amount and quality of irrigation water is not necessary and will be difficult to provide.

    Response - The amount of irrigation water in terms of "gallons per acre" or other units is needed so the reviewer can determine if the crop was grown under typical use conditions. It will be adequate to describe the quality of the irrigation water by providing a statement such as "water typically used to irrigate crops at the study site was used".

14. Comment - Curies per gram is not a realisitic unit.

    Response - This has been corrected. Activity is to be expressed as Curies/mole and disintegrations per minute per gram (dpm/g).

15. Comment - The MATERIALS section is too excessive.

    Response - Changes have been made based on suggestions from other commentors.

16. Comment - It is not necessary to know weather conditions at time of application.

    Response - As with any field study, it is mandatory to know the weather conditions, particularly at the time of pesticide application.

17. Comment - A map of the test plots is not necessary.

    Response - In the past, registrants have included maps (typically hand-drawn) showing the layout, topography and size of the test plot. The Agency reviewers have found these maps useful in reviewing the studies.

18. Comment - It is not necessary to include post-treatment crop maintenance information, such as use of fertilizers and other pesticides, as part of this study.

    Response - Inclusion of this information allows a better understanding of the study. Since post-treatment crop maintenance is a normal part of a rotational crop study, this cannot be construed to be a new data requirement and the information should be available.

19. Comment - Mention of "radiolabeled material" creates confusion with regard to this field study since it is to be conducted with "typical end use product".

    Response - Under special conditions, registrants have been able to justify use of radiolabeled material when conducting a field accumulation study in rotational crops (albeit in small, outdoor plots). Since this approach is becoming more prevalent, it is being discussed in this document.

20. Comment - When radiolabeled material is used, a detailed analysis of the formulation will not be needed. The results of the analysis of the formulated product is not necessary.

    Response - When radiolabeled material is used, the solvent and any other adjuvants are to be identified. Therefore, some analysis of this radio-labeled formulation will be needed. In most instances, a typical formulated end use product will be used. The analysis of the formulation is to include the % by weight of the active ingredient in the formulation and, for liquid formulations, the weight of active ingredient per unit of liquid measure. It is not necessary to chemically reanalyze the formulated product.

21. Comment - Soil characteristics in one-foot increments to four feet and the depth to the water table should not be required especially since the field study is being conducted in a typical use area. Taking soil cores to four feet may not be possible due to clay. For non-leachers, a soil profile to 12 inches should be adequate.

    Response - Conducting the study in a sandy soil may result in lower uptake of residues due to leaching of the pesticide residues below the root zone. Although a crop may be normally grown in a sandy soil, the same crop is probably grown in less sandy soils also. Therefore, to interpret the field rotational crop study, it is important to know the characteristics of the soil in which the study was conducted. If the information is not provided, then efficient review of the study may be compromised. If the information is submitted, then it should be included in the study according to this format. It is realized that soil samples may not be taken to four feet due to a hard clay layer. We agree with the comment regarding limiting soil sampling to 12 inches for non-leachers. However, the registrant's designation of their pesticide as a non-leacher may be in contradiction to the Agency's assessment.

22. Comment - Soil, climate and rainfall data are irrelevant to a rotational crop study.

    Response - These parameters have great impact on the results of a field rotational crop study. The study cannot be evaluated in the absence of this information.

23. Comment - Requesting information on the effects of other pesticides on degradation and uptake of the subject pesticide is similar to asking for tank mix data which the Agency is not currently requiring.

    Response - We agree. The request for this information has been deleted.

24. Comment - Storage stability data for every rotational crop is not necessary; data on only the parent crop should suffice. The paper by Egli (J. Ag. Food Chem., 30, (1982), p. 861) relating hydrolytic stability to stability in frozen crop samples should be considered. Why does the Agency have to know how long the samples will be kept in frozen storage?

    Response - We disagree. Consideration of the cited paper by the Residue Chemistry Branch indicates that residue stability in basic and acidic crops was not studied. Therefore, an indication of how long samples were kept frozen before analysis and how long they will be kept frozen for further work must be supported with storage stability data indicating the pesticide residues will be stable for the desired storage period.

25. Comment - In a non-radiolabeled field study, it is not practicable to provide a material balance.

    Response - We agree. Mention of the submission of this information has been deleted.

26. Comment - A description of the thawing procedure and dates of freezing and thawing are new requirements.

Response - The Agency is not asking the registrant to thaw or freeze anything. Therefore, it is not a new requirement! What the Agency is asking is should the registrant freeze or thaw samples that the procedures and dates of such be provided.

27. Comment - There is no need to provide soil sampling techniques.

Response - This information will provide the reviewer a better understanding of the study and allow for a more efficient review. If this information is submitted, it should be done so according to this format.

28. Comment - It is not necessary to express residues in terms of dry and fresh weight. This information can only be provided if the registrant can rely on tables of water content of crops. This information should only be provided for those commodities sold in both dry and fresh forms.

Response - Residues in terms of fresh and dry weight are needed only for those crops that enter commerce in both dry and fresh forms.

29. Comment - Rotational crops should be analyzed only for products of toxicological significance and not all degradation products. The radiolabeled rotational crop study will identify degradation products that occur under field conditions.

Response - We disagree. Products of toxicological significance cannot be identified until all products (toxic and non-toxic) are first identified. Therefore, the rotational crop study must include an analysis of all products in the crop. This information is then provided to toxicologists for an assessment of the toxicity of those products. If the radiolabeled rotational crop study is conducted under conditions simulating field conditions then the rotational crop will take up any compounds it would normally take up under field conditions.

30. Comment - The Agency seems to be requiring a radiolabeled field rotational crop study.

Response - The Agency is not requiring such a study but recognizes there are cases when a registrant can do a radiolabeled rotational crop field study that would satisfy the requirement to do both (1) the radiolabeled confined [165-1] and (2) the field [165-2] rotational crop studies. If a radiolabeled rotational crop field study results in no detectable uptake of residues by rotational crops, then it may satisfy the requirements for both 165-1 and 165-2. However, if the radiolabeled rotational crop field study does show uptake of residues by rotational crops, then 165-2 will be needed but the only compounds that will have to be analyzed for in 165-2 will be those detected in the radiolabeled rotational crop field study.

31. Comment - There is no need to provide a degradation scheme of the rotational crop residues.

    Response - Registrants often submit diagrams showing to what products their pesticide degrades. The reviewer finds these helpful in evaluating the study. More complicated diagrams (such as those showing involvement of plant enzymes or biochemical cycles) will not provide useful information.

32. Comment - A complete quality assurance package should not be required for this study.

    Response - We agree. This section reiterates the Guidelines.

33. Comment - Adopt the American Chemical Society method of arabic numerals for figures and roman numerals for tables.

    Response - This is a good suggestion. Registrants are encouraged to adopt any acceptable method but use it consistently since reviewers become confused when they review submissions containing different methods.

34. Comment - What is meant by " 'relevant' material should be placed in the appendices" ?

    Response - Relevant material is any material cited by the registrant that the registrant feels will aid in the review of the study but is not part of the study proper.

35. Comment - There is no need to resubmit studies cited in the appendix if those studies were previously submitted. Raw data, which is often voluminous, should not be necessary to submit. Standard analytical methods should be referenced and not described in detail. Only departures from standard methods should be discussed in detail.

    Response - Although it is not necessary to resubmit those studies and material, it will be to the registrant's advantage to have a hard copy of that referenced/cited material in the submission under review in the event the reviewer needs to refer to it. If the registrant elects to submit such hard copy, then it should be placed in the appendix.

§ § §

GUIDELINE

TITLE/COVER PAGE

Title page and additional documentation requirements (i.e., requirements for data submission and procedures for claims of confidentiality of data) if relevant to the study report should precede the content of the study formatted below. These currently proposed requirements are described in 49 FR (188) 37596 (9/26/85).

TABLE OF CONTENTS

This page should indicate the overall organization of the study and what material is on which page(s). Tables and figures should be included in the Table of Contents on an individual basis.

I. ABSTRACT

This section should also contain an overall summary of the study and mention, at least, the following points:

A. The chemical (use the name used throughout the report and indicate the formulation) was applied according to actual practice to the primary (treated) crop;

B. The primary crop and rotational crops were maintained according to actual practice;

C. Provide narrative or a table (with an appropriate title) that provides the following information:

Crop/ Crop part	Days between treatment and planting of rotational crop	Age of Crop at Time of Sampling	Rate lb ai/A	Residues (ppm)		
				Total	Parent	Products

D. Indicate unusual problems (such as technical difficulties or unusual weather) resulting in necessary deviations from the intended test protocol. Describe the effects of these deviations on the results of the study; and

E. Provide a name and a phone number of a contact person in the event the reviewer has technical questions about the study. (This is optional. However, provision of this information will facilitate efficient review in case of questions.)

II. INTRODUCTION

This section should open with a description of the purpose of the study, what requirement it is intended to satisfy and (if applicable) how it supports the position of the registrant. Background and historical information relative to the study should be placed in this section.

III. MATERIALS

This section and the methods section should be in narrative form and in the following order and should contain all details with regard to the materials, equipment, experimental design, field plots and procedures used in conducting the study. The registrant is encouraged to include drawings and photographs of the plot, equipment and of different phases of the study.

In this section, the following should be included:

A. Chemical

1. If radiolabeled material is used, provide the purity of the material, its activity in Curies/mole and disintegrations per minute per gram (dpm/g) and the site of radiolabeling; and

2. The composition of the product to be used in determining if it contains the claimed amount of active ingredient. Include the % (by weight) of the active ingredient and for liquid formulations, the weight of active ingredient per unit of liquid measure.

B. Site

1. A map of the test plots indicating their location, topography and size, and location and size of the control plots in relation to the test plots; an indication of whether the test plot contains a subsurface drainage system; the soil characteristics (% sand, % silt, % clay, % organic matter, pH, cation exchange capacity, moisture capacity) of the plot in one foot increments to a depth of four feet; the depth to the water table; and

2. A complete record of daily temperature and daily rainfall throughout the study and how they compare to temperature and rainfall over the past 10 years at the test site.

C. Crop

1. Crop and pesticide use history on the plot for the 5 year period preceding this study;

2. The date and technique of plot preparation prior to pesticide application;

3. The identity of the treated crop; a description of how and when the treated crop was planted; how and when the subject pesticide was applied; the weather (temperature, rainfall, windspeed and direction) and condition of the field at time of application; the formulation of the pesticide applied, adjuvants or other compounds added to the spray/application mixture; the application rate and the application technique. Also, provide a similar description for each of any additional applications made of the subject pesticide. Indicate how much pesticide

was applied in comparison to actual use rates and if application technique differed from label recommendations.

4. A description of any post-treatment crop maintenance such as use of fertilizers and other pesticides, irrigation (when applied and how much), tilling, weeding, etc.; and

5. A description of the source of irrigation water.

IV. TEST METHOD

A. General

1. A description of the soil sampling technique, depth of sampling, procedure and devices used and provide the pre- and post-application soil sampling schedule; provide the date of harvest of the treated crop and describe what is done to the plot after harvest in preparation for planting of the rotational crops;

2. The identity of the rotational crops planted in the study; a description of the procedure used in planting the rotational crops and the number of days between when the crops were planted in relation to when the plot was treated with the pesticide; a description of all procedures used in the maintenance of the rotational crops (as done for the treated crop), the sampling/harvest method and how many samples/replicates were taken; All dates should be provided in terms of "days from pesticide application".

3. A description of the handling of the samples from the time of taking of the samples until analysis with special attention to the conditions under which the sampled rotational crops were stored and the thawing procedure (if frozen); in addition, storage stability data to be used in determining if the pesticide residues are stable under the storage conditions; also, the dates the samples were frozen, thawed and analyzed;

4. If pesticide residues in the crop are stable when frozen, then indicate how long samples will be retained in the event additional analytical work is needed; and

5. Elaborate on the difficulties or special problems that arose during the study that necessitated deviation from the intended test protocol and on the effects the deviations had on the results.

B. Analytical Method

1. Each method used in this study is to be described fully and include method validation data, recovery and method sensitivity data, sample chromatograms and sample calculations. Preparation and handling of the sample throughout the method should be described in detail. Note that methods for degradation products may also be needed.

2. Identify the instrumentation, equipment and reagents used and the operating conditions of the instrumentation. If the extraction/clean-up procedure is complex, then a flow diagram of it should be submitted.

3. Identify the plant fractions analyzed in the study, such as grain, chaff and straw in the case of small grains and root and aerial (leafy) portions in the case of root crops.

V. RESULTS/DISCUSSION

A. This section should contain the scientific results of the study. Narrative and tables describing the steps taken in determining the pesticide residues in the soil and crop samples should be presented. All graphical presentations of the data should be accompanied with tables of the actual values from which the graph was constructed. Include results of the analysis of the control plots.

B. This section should contain a table of structures and chemical names/designations for the parent compound and degradation products discussed in the study.

C. The registrant should be sure that the rotational crops are analyzed for the degradation products found in the radiolabeled rotational crop study. It may be necessary to also analyze the rotational crops for other degradation products found and identified in the hydrolysis, photolysis and aerobic soil metabolism studies if the radiolabeled rotational crop study was not conducted under conditions simulating field conditions.

D. Residues found in the rotational crops are to be reported in terms of crop fresh weight and in terms of crop dry weight (if the crop enters commerce in dry form).

E. If the parent pesticide or its degradation products are metabolized by the rotational crop, then the identity of those products is to be provided.

VI. CONCLUSION

Provide discussion as to the significance of the residues (if any) taken up, at what intervals residues are taken up by rotational crops (in which crop fractions and at what levels) and at what interval no residues can be expected to be taken up by rotational crops.

VII. CERTIFICATION

A. Signatures of each of the senior scientific personnel responsible for the study; and

B. Certification by the applicant that the report is a complete and unaltered copy of the report provided by the testing facility.

VIII. TABLES/FIGURES

It is recommended that tables and figures be numbered using arabic numerals for figures and roman numerals for tables.

IX. REFERENCES

X. APPENDIX(ES)

Reprints of methods and other studies cited, actual results of analyses (raw data), copies of relevant letters and memos and other material not fitting in any of the other sections and that support the petitioner's case should be placed here.